

**REMARKS**

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

***Status of the Claims***

Claims 1-4, 6, and 10-16 are currently pending in the present application. The Office Action is non-final. Claim 13 was rejoined to elected Group I. Claims 14-15 remain withdrawn from further consideration as being directed to a non-elected invention. Claims 5 and 7-9 were cancelled without prejudice or disclaimer. Claim 16 is new. Support for claim 16 can be found on page 17, line 15, of the present specification. Claims 1-4, 6 and 10-13 have been amended without prejudice or disclaimer. No new matter has been added by way of amendment. For instance, Claim 1 was amended to include SEQ ID NO: 1 to refer to Alcadein  $\alpha$  based on the text on page 9, lines 4-7 of the present specification. Additionally claims 1-4 were amended to correct typographical errors. Claims 1-4 and 6 were further amended to include the term "isolated," which has support at page 8, line 22, to page 10, line 11, and within the examples of the specification. Also, claims 2 and 3 were amended to include the specific cleavage sites for each of the N and C termini. Claim 4 was amended to include both the specific cleavage sites for the N and C termini. Support for claims 2, 3 and 4 can be found on page 12, line 17, and page 13, line 10, of the present specification. Support for amended claim 10 can be found on page 2, line 9, page 3, line 13, to page 4, line 5, page 17, lines 14-17, page 50, lines 5-11, and page 53, line 24, to page 54, line 2, and the examples. Support for amended claim 12 can be found on page 16, line 10 of the specification. Finally, support for amended claim 13 can be found on

page 16, line 10, and page 23, lines 9-16 of the specification. Thus no new matter has been added.

Based upon the above considerations, entry of the present Amendment is respectfully requested.

***Claim Objections***

Claims 1-13 are objected to due to reciting non-elected subject matter. Further, claims 1-5 are objected to due to misspellings within the recited claims. Applicants have cancelled claims 5 and 7-9, without prejudice or disclaimer, thus obviating the objection to these claims. Claims 1-4, 6 and 10-13 have been amended, without prejudice or disclaimer, to remove the non-elected subject matter and to correct misspellings in claims 1-4, as the Examiner recommended. Applicants respectfully request reconsideration and withdrawal of the present objection.

***Issue Under 35 U.S.C. § 101, Non-Statutory Subject Matter***

Claims 1-6 stand rejected under 35 U.S.C. § 101 since the claimed invention is directed to non-statutory subject matter. Applicants have cancelled claim 5, without prejudice or disclaimer, thus obviating the objection to this claim. As suggested by the Examiner, Applicants have amended claims 1-4 and 6, without prejudice or disclaimer, to recite an "isolated peptide." Support for the above amended claims can be found at page 8, line 22, to page 10, line 11, and within the examples of the specification. Applicants respectfully request reconsideration and withdrawal of the present rejection.

***Issue Under 35 U.S.C. § 112, Second Paragraph, Indefiniteness***

Claims 1-13 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner asserts that claims 1, 4 and 5 are vague and indefinite since the term, "Alcadein  $\alpha$ ", appears to be novel, and without a reference to a precise amino acid sequence identified by a proper SEQ ID NO, the metes and bounds of "Alcadein  $\alpha$ " cannot be determined.

Regarding claims 1-6, the Examiner also asserts that the claims are vague and ambiguous since the claims recite references to potential sites of cleaving "Alcadein  $\alpha$ ," portions of the extracellular domains and enzymes that cleave Alcadein  $\alpha$ . The Examiner indicates that language absent an explicit reference to the molecular structure renders the claims vague and indefinite.

Applicants have cancelled claims 5 and 7-9, without prejudice or disclaimer, thus obviating the objection to these claims.

Although Applicants disagree, in order to further prosecution, Applicants have amended claim 1, without prejudice or disclaimer, to include SEQ ID NO: 1 to refer to Alcadein  $\alpha$ , based on the text on page 9, lines 4-7 of the specification. Applicants respectfully submit that the relationship between Alcadein  $\alpha$  and the identified sequences in claims 1, 4 and 5 has been made.

Further, Applicants have amended claims 2, 3 and 4, without prejudice or disclaimer, to include the specific cleavage sites for each of the N and C termini for claims 2 and 3, as well as amend claim 4 to include both the specific cleavage sites for the N and C termini. Support for

claims 2, 3 and 4 can be found on page 12, line 17, and page 13, line 10, of the present specification.

Applicants respectfully submit that the amended claims resolve the above rejection and particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully request reconsideration and withdrawal of the present rejection.

***Issue Under 35 U.S.C. § 112, Second Paragraph, Indefiniteness***

Claims 7-12 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner suggests that claims 7-12 are incomplete for omitting essential steps as to what is encompassed by “a process of detecting...the peptide” and the final step that stands for achieving the goal recited in the preamble of the claims, such as what result means diagnosis of Alzheimer's disease (AD). Further, the Examiner asserts that claims 7 and 10 are vague and ambiguous for recitation of “an animal”. The Examiner also asserts that the relationship between diagnosis of AD and “an animal” is not obvious because Alzheimer's disease is known as an exclusively human disease.

Applicants have cancelled claims 7-9, without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants respectfully traverse as to the remaining claims.

Although Applicants disagree, in order to further prosecution, Applicants have amended claim 10, without prejudice or disclaimer, by adding an “obtaining” step, defining a “sample” as

body fluid or tissues taken from a subject, and indicating an Alzheimer's diagnosis step to complete the claim.

Also, Applicants have amended claim 11, without prejudice or disclaimer to be consistent with the definition of "sample." Additionally, Applicants have amended claim 12, without prejudice or disclaimer, to add from page 16 of the specification the definition of a high molecular weight peptide.

Finally, the Examiner asserts that for claim 13 there is insufficient antecedent basis for the limitation "molecular species of the secreted peptide in claim 1." Also, the Examiner also asserts that claim 13 recites the limitation "change," which is a relative term for which no point of reference is provided within the claim. Applicants respectfully traverse.

Although Applicants disagree, in order to further prosecution, Applicants have amended claim 13, without prejudice or disclaimer, by removing from claim 13 "secreting" and replacing it with "containing." Applicants also removed the additional "secreted" from the claim. Finally, in order to define "change" within the claim, Applicants have amended claim 13 to add the definitions that can be found on pages 16, lines 10-13 and page 23, lines 9-16 of the specification.

Applicants respectfully submit that the amended claims resolve the above rejection and particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully request reconsideration and withdrawal of the present rejection.

***Issue Under 35 U.S.C § 112, First Paragraph, Enablement***

The Examiner has cited the following 35 U.S.C. § 112, first paragraph, rejections below.

Claims 7-13 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement.

The Examiner suggests that the above claims contain subject matter not described in the specification in such a way as to enable one skilled in the art to make or use the invention commensurate within the scope of the claims.

Applicants have cancelled claims 7-9, without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants respectfully traverse as to the remaining claims.

Although Applicants disagree, in order to further prosecution, Applicants have amended claim 10-13, without prejudice or disclaimer, as described in the previous rejections, above.

Applicants respectfully submit that the pending claims encompass subject matter that is fully enabled by the present application. Applicants respectfully request reconsideration, and subsequent withdrawal of the present rejection.

In view of the above remarks, Applicants believe the pending application is in condition for allowance.

**CONCLUSION**

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.


In view of the above remarks, it is believed that claims are allowable.

Should there be any outstanding matters within the present application that need to be resolved, the Examiner is respectfully requested to contact Paul D. Pyla, Reg. No. 59,228, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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